Spirometrics

FLOWMATE V PLUS USER'S MANUAL

Copyright 2000, 2004

P O Box 680, 22 Shaker Road
Gray, ME 04039 USA

http://www.spirometrics.com

REV 03

February 2004

Doc. #: 20003 Rev. 3

FLOWMATE V PLUS USER'S MANUAL
Table of Contents

CHAPTER 1	1
Introduction	1
Warranty Card	3
CHAPTER 2	5
Intended Use	5
Warnings and Precautions	5
Setting Up	6
Loading Paper	6
Factory Settings	8
Customization Routine	10
Setting Time/Date	11
CHAPTER 3	12
Calibrating the Spirometer	12
CHAPTER 4	14
Operating the Flowmate V Plus	14
Summary of Operations	16
CHAPTER 5	17
Testing	17
Patient Preparation	17
Entering Patient Data	18
Forced Vital Capacity (FVC) Testing	20
Summary of FVC Test Results	22
Maximum Voluntary Ventilation (MVV) Testing	23
Vital Capacity (VC) Testing	25
Methacholine Challenge	27
Post-Bronchodilator Testing	30
Retrieving Test Results	31
Erasing a Test	32
Erase Procedure	32
Saving Patients to Diskette	33
Summary Reports	33
CHAPTER 6	35
Maintenance	35
Diagram Handle Assembly	36
Cleaning and Sanitizing	37
Troubleshooting	38
Calibration	40
Patient Storage	41

CHAPTER 7 42

Specifications 42

CHAPTER 1

INTRODUCTION

CONGRATULATIONS...on your purchase of a Spirometrics FLOWMATE V PLUS spirometer. Built by the Spirometrics Medical Equipment Company of Maine, the FLOWMATE V PLUS represents the newest technology in the medical equipment field. Its ease of operation and durability will provide years of service.

Spirometrics is committed to designing products that meet the highest standards of quality instrumentation for pulmonary function testing. We have designed the FLOWMATE V PLUS to take advantage of new developments in computers and software for years to come.

Please read this manual carefully before setting up and operating your new FLOWMATE V PLUS.

STOP!

BEFORE SETTING UP, PLEASE COMPLETE THE ATTACHED WARRANTY CARD ON PAGE THREE (3) TO ENSURE THAT YOUR WARRANTY RIGHTS ARE COVERED.

For the device warranty to be in effect, the attached warranty card must be returned to Spirometrics Medical Equipment Co. for warranty registration. Please take this time to fill out the enclosed postage paid warranty card. You may also register your warranty by calling 800-767-0004 or faxing the information to 207-657-4123.

All Spirometrics spirometers are warranted to be free from defects in workmanship and material for a period of TWELVE MONTHS from the date of purchase as validated by the return of the warranty card. If the warranty card is not returned or otherwise registered by phone, the TWELVE MONTH warranty begins from the date of manufacture.

During the warranty period, any and all original parts and or workmanship proven to be defective will be replaced or repaired at an authorized service center provided the equipment has been operated and maintained in accordance with the instructions contained in the Operator's Manual. This warranty applies to the original user only, is not transferable, and does not extend to any product or component which has been repaired or altered by anyone other than personnel authorized by Spirometrics. This warranty is in lieu of and excludes any warranty as to merchantability and all other warranties expressed or implied and does not cover consequential damages due to improper use or application of the product.

This page set aside for the WARRANTY CARD insert.

This page set aside for the WARRANTY CARD insert.

CHAPTER 2

INTENDED USE

The FLOWMATE V PLUS spirometer is intended for use with adult and pediatric patients for the diagnosis and monitoring of pulmonary disorders. The company disclaims responsibility for all other uses, and the user agrees to assume liability for damages resulting from non-intended use or operator error by the user or user's employees.

WARNINGS AND PRECAUTIONS

The following warnings and precautions must be heeded at all times:

- **Use a genuine Spirometrics filter/mouthpiece (Spiro-Filter) to ensure proper accuracy, reduce the risk of patient cross-contamination and to protect the internal sensor element. Replace the Spiro-Filter after each patient.**
- **When the unit is not used for extended periods of time, set the printer lever in the down position. If the printer is left for a long time with the printer head engaged, the printer head may become deformed and print quality cannot be guaranteed. See the LOADING PAPER section later in this chapter.**
- **Clean the EASY CLEAN cartridge regularly to insure the long-term stability and accuracy of the instrument. Please refer to Chapter 6 MAINTENANCE AND TROUBLESHOOTING for proper cleaning procedures. Do not attempt to clean the unit with abrasives or solvents. Do not autoclave any portion of the unit.**
- **Never immerse any component of the system in water or other liquids with the exception of the EASY CLEAN cartridge.**
- **The FLOWMATE V PLUS has built-in calibration capability. The 1994 ATS standard on spirometry recommends daily calibration of this instrument or more frequently as appropriate.**
- **Accurate and effective use of the FLOWMATE V PLUS depends on correct application of well established spirometry practices.**
- **Do not operate the unit in a flammable or explosive atmosphere.**
- **Insure that the EASY CLEAN cartridge is properly installed as described in Chapter 6 MAINTENANCE AND TROUBLESHOOTING.**
- **Do not drop the sensor handle. The FLOWMATE V PLUS handle is a sensitive measurement device. Improper handling could affect the accuracy of its reported results.**

SETTING UP

1. Remove FLOWMATE V PLUS from box and unwrap packing materials. Check the list to make sure all items listed are in the box.
    - 1 - FLOWMATE V PLUS
    - 1 - Thermal paper roll
    - 1 - Power cord
    - 1 - Power supply
    - 1 - Operator's manual
2. Place FLOWMATE V PLUS on flat surface.
3. Take the five (5) pin DIN connector end of power supply cord and plug into the power input of FLOWMATE V PLUS.
    - Take the IEC320 connector end of power cord and plug into the power supply.
    - Plug AC cord into an outlet.
4. Insert disposable filter onto EASY CLEAN Cartridge.

LOADING PAPER

The FLOWMATE V PLUS is equipped with an internal thermal printer, and an external parallel printer connection. Before using, the thermal paper will have to be loaded.

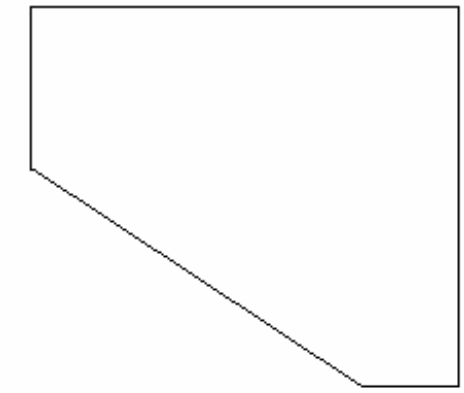
1. Cut the printer paper with a diagonal cut as shown at the end of this section. Position the printer lever in the down position. This releases the printer platen to ease the threading of paper into the printer.
2. Place paper roll into holder by pulling either of the spring-loaded clips.
3. Insert paper into the printer slot going in from the top. When the paper meets with resistance against the paper roller, press the PAPER key on the keypad. Pressing once and releasing will advance the paper one line at a time. Pressing the PAPER key down and holding it for 4 seconds will initiate the printer continuous feed mode until the PAPER key is released.

    Note: The printer has an internal paper sensor located on the right hand side. If when inserting the paper to thread the printer, paper does not cover

the sensor, the printer will not advance when pressing the paper key. It will beep to indicate that the paper is not detected. Please remove and try again.

4. Once the paper has begun to feed through the printer, create enough lead to check the paper alignment through the printer by lining up the edges of the paper through the printer with that to be fed into it from the back. Shift as necessary to align.
5. Set paper release toggle to up position to engage printer platen onto the paper. ***CAUTION:¸ When the unit is not used for extended periods of time, set the printer lever in the down position. If the printer is left for a long time with the printer head engaged, the printer head may become deformed and print quality cannot be guaranteed.***
6. Press paper advance.

We suggest cutting the thermal paper roll on a diagonal and leave about an inch on the right hand side to ease the paper detection and threading of paper into the printer:



Now your FLOWMATE V PLUS is ready to operate.

BEFORE SETTING UP, PLEASE COMPLETE THE ATTACHED WARRANTY CARD ON PAGE THREE (3) TO ENSURE THAT YOUR WARRANTY RIGHTS ARE COVERED.

FACTORY SETTINGS

The FLOWMATE V PLUS comes ready to operate with settings already configured at the factory. Upon initial start-up, the FLOWMATE V PLUS must be configured for the language to use. Select the language for use by entering the number corresponding to the language on the display. Selecting number 1 by pressing the **1** key will enable English as the displayed language. To customize settings, see CUSTOMIZING YOUR FLOWMATE V PLUS in the next section. The standard configuration chart listing the default settings and options on the FLOWMATE V PLUS follows.

STANDARD CONFIGURATION CHART

Function	Standard Configuration	Options
1. Language Selection	Selected by user on initial start-up 1. Select English Language 2. Seleccione el idioma Español 3. Wählen Sie Deutsche Sprache aus. 4. Selezionare la lingua italiana 5. Choisir langue française	 English Spanish - Español German - Deutsch Italian - Italiano French – Français
2. Autoprint Test	No	Yes
3. Use Inspiratory Calibration	No	Yes
4. Selected Printer	Internal	Epson FX (9) Epson LQ (24) Epson Color IBM Proprinter IBM Pro X24 HP Laser Jet 2 DeskJet 4-ink
5. Time format (hr)	12	24
6. Date format	American (mm/dd/yy)	European (dd/mm/yy)
7. Use Location I.D. #	No	Yes

8.Enter Current Location I.D. #	Blank	(up to 16 digits)
9. Prompt daily for Loc. I.D. #	No	Yes
10. Report Format	Short	Expanded
11. Use ATS Hand Measure	Yes	No
12. Print Vol/Time Curve	Yes	No
13. Print Flow/Vol Loop	Yes	No
14. ATS flat 0.2L Variability	Yes	No (uses 5% comparison)
15. Graph Best Test Curves	Both	VT Curve FV Loop None
16. Superimpose each effort on graph	No	Yes
17. Print diagnostic interpretations	Yes	No
18. Print COPD Risk	Yes	No
19. Print Lung Age	Yes	No
20. Selected Normals	Composite	Knud 76 Knud 83 Crapo Morris Hsu ECCS Lam
21. Height in (units)	in.	cm.
22. Record Patient Weight	Yes	No
23. Weight in (units)	Lbs	kgs
24. Extrapolate Predicted (if outside range)	No	Yes

25. Inhalation Challenge settings OK?	Inhalations per concentration: 5 Methacholine concentration: (#2) = .025mg (#3) = .250 (#4) = 2.500 (#5) =10.00 (#6) =25.00 Lower limit of normal Default=08 Cum. Dose = ?	Custom options
26. Print Out Settings	No default	YES or NO

NOTE: It is strongly suggested that you print out and keep handy a copy of your customization settings.

CUSTOMIZATION ROUTINE

CUSTOMIZING SETTINGS:

To customize the settings of your FLOWMATE V PLUS, simply cycle through each setting. To display the options for each setting, press the left or right ARROW keys. Press ENTER or the DOWN arrow to move to the next setting without changing the previous setting.

EXAMPLE

To change the setting under the “Graph Best Test Curves” from “Both” to “None”, follow these steps:

1. From MAIN MENU, select 2 - CUSTOMIZATION
2. Press ENTER to cycle through settings until you reach “Graph Best Test Curves”.
3. Press either left or right ARROW key until display shows “None”.
4. Press ENTER to change setting and to continue through subsequent settings.

SETTING TIME/DATE

It is important to make sure the time and date are correct since test records will display such information for each test. To set the time and/or date, perform the following steps:

1. From MAIN MENU select 4 - TIME/DATE.
2. Based on the time display format you selected during customization, screen will display hour-minute-second values with cursor on HOUR.
3. Enter value from 01 to 12 (for 12 hour format or for 24 hour format, 01 to 24) for hour, or use side ARROW keys to select appropriate setting.
4. Cursor automatically moves to MINUTES. Enter value from 00 to 59.
5. Cursor automatically moves to SECONDS. Enter value from 00 to 59 or press the ENTER key to accept value that is there.
6. Cursor will drop down to the date field. Press the appropriate numbers on the keypad, as when setting time.
7. When date is set, press ENTER.
8. Screen will prompt: ***"Accept time and date?"*** YES or NO.
9. If YES, you'll go back to the MAIN MENU, if NO you'll return to TIME/DATE for modifications.

NOTE: To maintain the internal rechargeable battery's ability to keep accurate date and time, it must be charged from 20 – 24 hours during a thirty day cycle. The battery will only charge when the FLOWMATE V PLUS is actually turned on.

CHAPTER 3
CALIBRATING THE FLOWMATE V PLUS

CALIBRATING THE SPIROMETER

Calibrating the FLOWMATE V PLUS ensures accurate test results. The American Thoracic Society (ATS) recommends daily calibration and at intervals throughout the day when performing a large number of tests. When calibration is out of date, meaning that a calibration has not been performed on the same day that testing is to take place, a message will appear on the screen: ***"Calibration out of date."***

To calibrate your FLOWMATE V PLUS, first set up your calibration syringe in the following manner:

- You will need a calibration syringe (part #2125) and a calibration syringe adapter (part # 30-0015).
- Connect the adapter seal to the end of the calibration syringe.
- Connect the flow sensor and filter firmly to the calibration syringe.

The FLOWMATE V PLUS allows calibrations in both the inspiration and expiration volumes. Each mode is a two step process, the first step gives the unit a reference, the second checks the volume measured.

NOTE: The inspiratory calibration is an optional choice during CUSTOMIZATION. If not selected, the expiratory calibration factor will be used for both.

To calibrate the spirometer, follow these steps:

1. From the MAIN MENU press 3 - Calibration.
2. Screen prompts***: "Enter environmental conditions."*** Or set to the average where testing is to be conducted and scroll through.
    - Air temperature in °F (50-104) or °C (10-40)
    - Barometric Pressure in inches (20-35) or mmHg (500-900).
3. Select the calibration to perform:

    1= Flow Sensor Expiratory

    2=Flow Sensor Inspiratory

4. Screen prompts**: *"What is the test syringe volume? (Enter volume: 1-9 liters)"***
5. ENTER correct syringe volume, i.e., 3 liters
6. At Flow Sensor Calibration screen press ENTER when ready to inject.
7. Screen will display a sliding bar graph representing the air flow. Keep the indicator within boundaries of target range.

HELPFUL HINT:

In keeping with the American Thoracic Society's 1994 Standardization of Spirometry and good quality control procedures, it is recommended that the linearity of the flow sensing pneumotach should be checked on a weekly basis. This can quickly and easily be accomplished by injecting your calibration syringe at three different flow rates during a Follow-up Injection. As an example, taking a three liter syringe and injecting it 1, 3, and 6 seconds would create flow rates of 3 l/s, 1 l/s, and 0.5 l/s respectively. Answer YES to the question "Do You Want To Check Calibration Again?", and repeat for each subsequent follow-up injection desired to check. The volumes measured at the flow rates used, should all be within the stated +/- tolerance to be considered acceptable.

STOP!

DID YOU COMPLETE THE ATTACHED WARRANTY CARD TO ENSURE THAT YOUR WARRANTY RIGHTS ARE COVERED? IF NOT, PLEASE DO SO NOW!

CHAPTER 4

OPERATING THE FLOWMATE V PLUS

FLOWMATE V PLUS KEYPAD

CONTROL KEYS

PAPER — From the MAIN MENU pressing this key advances paper one line at a time.

ARROW KEYS — Pressing the UP or DOWN arrow moves cursor appropriately. Pressing the LEFT or RIGHT arrow selects and deselects options when customizing, otherwise moves cursor in appropriate direction.

SEND — Pressing this key transmits unsaved data to diskette.

OUTPUT KEYS

These keys control the output of test results and summaries on the display and the printer.

DISPLAY — From the MAIN MENU, pressing this key gives you a readout on the memory remaining in the FLOWMATE V PLUS. In other modes, pressing this key will change the display on screen.

PRINT — From the MAIN MENU, pressing this key will give you six choices:

1. All patients in memory.
2. All patients on disk.
3. A single patient.

Batch print: (0 of 32 in list)

4. Add patient to list
5. Remove patient from list.
6. Print List

Pressing 1 will give you a printed readout on every patient in the machine's memory.
Pressing 2 will give you a printed readout on every patient on the disk.
Pressing 3 will prompt the machine to ask you for specific identification numbers of the subject of printed readout.
Pressing 4 will give you prompts to add a patient's ID number to the list.
Pressing 5 will give you prompts to delete a patient's ID number from the list.
Pressing 6 will print a Best Test Summary for all patients on the list.

From the TEST MENU, pressing the PRINT key prints out a report of the current test if viewing results of a specific test, or will prompt you to select a test by number for that particular patient.

NOTE: If you selected AUTOPRINT during customization, each test result will automatically be printed out at the conclusion of each test.

ERASE

From the MAIN MENU, pressing the ERASE key will prompt the following three choices:

1. Erase all patient records in memory? Are you sure? (Press YES or NO). By pressing YES you will erase all patient records stored in memory. Pressing NO will take you back to the MAIN MENU.

2. Erase some records in memory? This will call up on the screen patient records in sequence and give you a choice of YES or NO with each individual record.

To go back to MAIN MENU without erasing anything, press 0.

From the TEST MENU, pressing the ERASE key offers a selection of tests on each particular patient to be erased. As a safety

precaution, the FLOWMATE V PLUS will always ask you if you are sure you would like to erase the data you have selected.

SUMMARY — From the MAIN MENU, pressing the SUMMARY key will display a listing of all patients in the machine's memory. From within a patient's record, pressing the SUMMARY key will print out the Best Test Summary.

NEXT KEYS

These two keys "schedule" the operation of the FLOWMATE V PLUS

PATIENT — Pressing this key returns you to the MAIN MENU.

TEST — Pressing this key offers the prompt: Which TEST would you like? You may select one of four tests: FVC, MVV, VC, or Chal.

NOTE:	Pressing the TEST key from the MAIN MENU will create a "J. Doe #xxx" patient. See Chapter 5

***SUMMARY OF OPERATIONS**:*

Follow these easy steps to operate the FLOWMATE V PLUS:

1. Turn power switch (on back of machine) to ON. (0=Off I=On)
    - Upon power-up, the unit initially checks the integrity of the memory and the program. Then the logo screen will appear showing the unit's time and date settings. If incorrect, update by following the procedures outlined in CUSTOMIZATION, Chapter 2.
2. After cycling through the initial checks, screen will display MAIN MENU.
3. At the MAIN MENU screen, press the appropriate number on the key pad:
    - 1 -- PATIENT.
    - 2 -- CUSTOMIZATION
    - 3 -- CALIBRATION
    - 4 -- TIME/DATE

CHAPTER 5

TESTING

Before testing a patient, the patient should be prepared by making him/her feel comfortable and relaxed. This can be accomplished by explaining and demonstrating the procedures to be undertaken. The following guidelines may be followed in preparing a patient.

PATIENT PREPARATION

Explain

> ...A spirometer is used to assess lung function. The purpose of the spirometry test to you (the patient): is to measure how hard and how fast you can breathe and how much air is in your lungs. If properly performed the test results can indicate the presence or absence of an obstructive or restrictive lung disorder.

Direct

> ...the patient to:
> - Remove or loosen tight clothing such as tight collars or necktie.
> - Remove dentures (optional).
> - Stand in front of the spirometer. (Patient should not take the test sitting down unless he/she can not stand).
> - Elevate chin and extend neck slightly.
> - Use a nose clip, if available. (Have the patient pinch his/her nose if unavailable) See the FLOWMATE V PLUS Accessories.

Demonstrate

> ...the procedure yourself:
> - Take the deepest breath possible.
> - Place mouth and teeth tightly around the mouthpiece.
> - Do not block the opening with the tongue.
> - Then, blow out as hard and fast and completely as possible- getting all the air out. If a loop is being tested, inhale deeply back through the sensor.
> - Pull away from the mouthpiece and relax.

Instruct

...the patient firmly and enthusiastically: "Take a good deep breath. Pull it ALL in. Push it all OUT!...Blow as hard as possible and then inhale back in... Good job!"

ENTERING PATIENT DATA

Before beginning tests with a new patient, the FLOWMATE V PLUS will need some information on the patient for predictions and easy test recall later. The data is stored in memory and does not have to be re-entered before each subsequent test. However, you can perform tests without filling out the patient data field, simply by pressing the TEST key from the MAIN MENU. See NOTE following step 3.

To enter appropriate patient data, perform the following steps:
1. If needed, turn on FLOWMATE V PLUS by depressing the POWER switch at rear of instrument.

2. From the MAIN MENU press 1.

3. The screen prompts: ***"Patient information (or press test) Enter I.D. number ."*** Enter patient's I.D.(identification) number, up to 16 digits, including periods and slashes. The number can be the patient's social security number or any other appropriate identification. Be sure that each patient has his or her own number. Do not start a patient's ID# with a period.

NOTE: If you press the TEST key at this point, you will jump directly to the TEST SELECTION MENU without having to enter patient data. If you do this the FLOWMATE V PLUS will display and print test results for "J. Doe. xx." Such test results will not include predicteds, percent of predicteds, or interpretations, since there is no patient data on which to base such results. In addition, the patient's test results will only be stored as "J. Doe xx" when you move on to the next patient. To reprint later, batch print all must be selected. Individual "J. Doe's" can not be recalled for additional testing.

4. After entering an I.D. number and pressing ENTER, the FLOWMATE V PLUS will search its base memory for that I.D. number.

- If it is found, the display will prompt: ***"Is this Post Bronchodilator testing?"*** (YES or NO?). Answer NO unless you are performing Post Bronchodilator testing (see directions at end of this chapter).
- If it is not found, the display will prompt: ***"Create new patient using I.D. number?"*** If you press YES, the screen will change to the patient questionnaire.

- If NO, the display will prompt: ***"Load patient from diskette?"*** If patient information is on diskette, you would utilize this option for recalling a previously tested patient that has been stored on diskette.

NOTE: If you are unsure of which diskette patient is located, you will have an option to check several diskettes.

5. Enter the age of the patient, up to 2 digits. The patient's age must be between 1 and 99, press ENTER.

6. To enter the patient's SEX, use the LEFT or RIGHT ARROW keys to choose Male or Female. press ENTER.

7. To enter the patient's RACE, use the LEFT or RIGHT ARROW to cycle through the choices (caucasian, black, non-caucasian, asian, hispanic), then press ENTER.

8. To enter the patient's HEIGHT in either centimeters or inches, enter the appropriate numbers, then press ENTER.

9. To enter the patient's weight in pounds or kilograms, enter the appropriate numbers, then press ENTER.

10. The display will prompt: ***"cigarettes per day".*** Enter the number of cigarettes per day the patient smokes, then press ENTER.

11. Accept changes by pressing ENTER/YES if the changes are appropriate. If you need to make further changes, press NO and the procedure will begin anew.

12. TEST MENU will then be displayed with the prompt: ***"Which test would you like?"*** You are now ready to begin testing by selecting the test by number.

FORCED VITAL CAPACITY (FVC) TEST

PROCEDURES

Before beginning the test, DEMONSTRATE the FVC maneuver so the patient has a clear idea of what is expected of him/her.

1. INSERT new mouthpiece and filter into the flow sensor.
2. SELECT from the test choice menu by pressing NUMBER 1
3. INSTRUCT patient in the maneuver with the following suggestions:
    - Take as deep a breath as you can and hold it.
    - Put mouthpiece in your mouth, past your teeth, and form a tight seal with your lips. Make sure your tongue is not blocking the mouthpiece.
    - Now blast the air out as hard and fast as possible.
    - Inhale as deeply and quickly as possible through the mouthpiece.
    - Remove the mouthpiece.

4. While patient is performing the test, FLOWMATE V PLUS displays both the Volume/Time Curve and the Flow/Volume Loop, allowing the patient to view a visual display of the test results.
5. When flow has stopped there will be an audible "beep-beep-beep" and the screen displays the message: ***"Was the Patient Effort Acceptable? (press YES or NO)"***
6. Press YES or NO.
    - If YES the unit computes, displays and stores the test results. If AUTOPRINT option has been activated, the report is printed out.
    - If NO, the unit abandons the test and the patient can try again until clinician is satisfied with effort.

NOTE: Patient effort is acceptable if the patient:
- Started with the deepest possible inspiration
- Exhaled maximally with a good, fast start.
- Inhaled maximally after the expiration.
- Inhaled and exhaled smoothly, with no coughing.

The FLOWMATE V PLUS may display a message indicating the test was too short or that the start was too slow, based on criteria established by the American Thoracic Society. However, the unit will still store such a test.

When a patient's test is accepted, the FLOWMATE V PLUS displays the test result.

ILLUSTRATION

FVC TEST RESULTS SUMMARY page 1

Index	Units	Meas.	Pred	%Pred	Var.
FVC	L	5.52	5.67	97	2.3
FEV1	L	3.96	4.65	85	0.5
FEV1/FVC	%	70.0	82.6	85	1.9
FEV25-75	L/S	2.6	4.8	55	7.6
PEF	L/S	10.6	9.8	107	9.8

Forced Expiratory Time: 12.15 sec

Press DOWN to show page 2

Press DISPLAY to show graphs

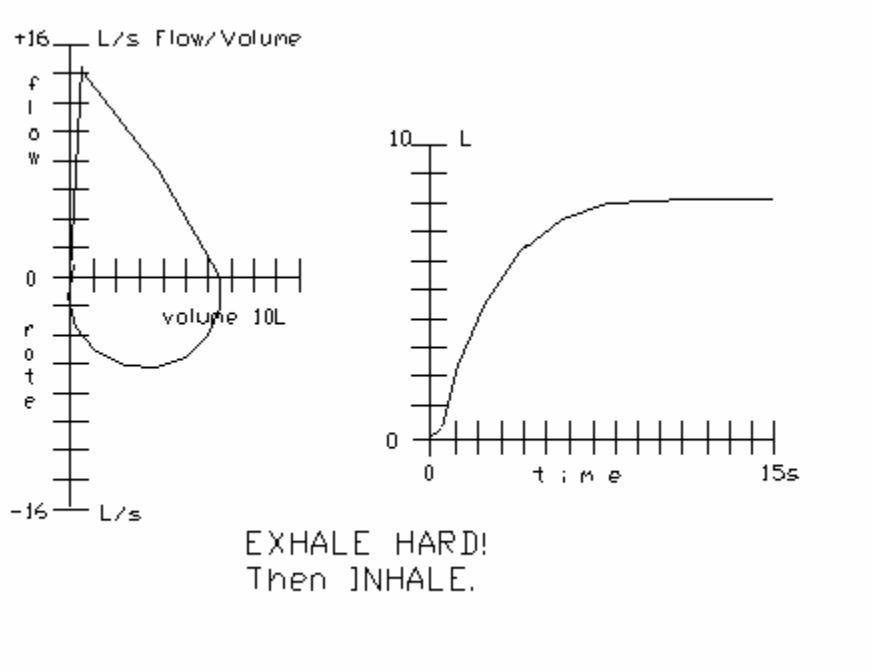
To start another test, simply press TEST, then select test by number.

SUMMARY OF FVC TEST RESULTS

FVC VOLUME-TIME CURVE (ILLUSTRATION)

The Volume vs. Time curve represents the volume of air through the mouthpiece over a period of time. The left axis represents volume in liters at BTPS (Body Temperature, standard Pressure, and Saturated with water vapor at these conditions). The bottom axis is time in seconds.

The Volume-Time Curve shows two of the most important indices, Forced Vital Capacity (FVC) and Forced Expiratory Volume at one second (FEV_1) See Chapter 7 for a complete listing of test indices.



The Flow Volume Loop represents flow along the y-axis and volume along the x-axis at BTPS.

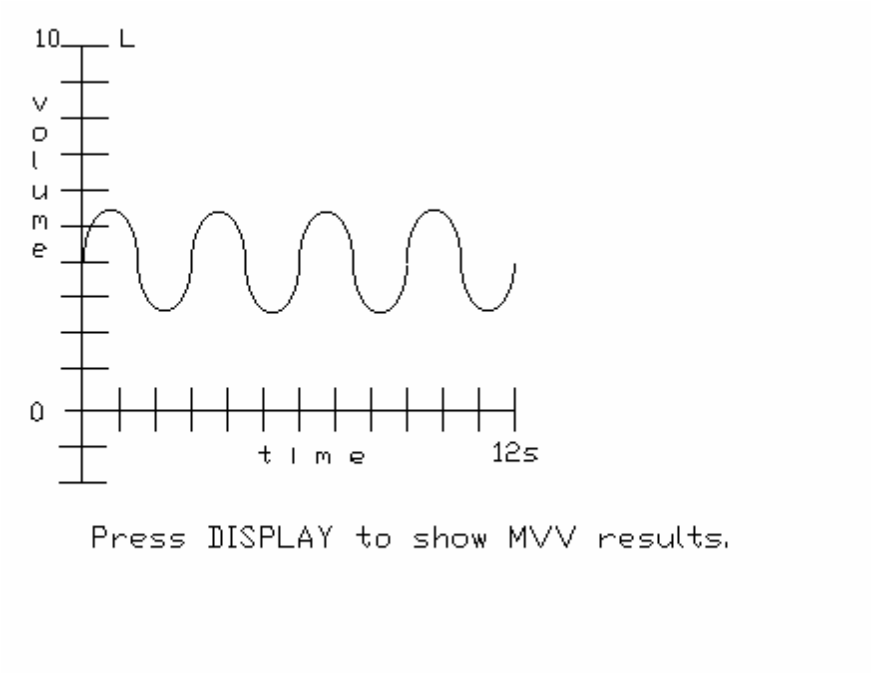
MAXIMUM VOLUNTARY VENTILATION TEST (MVV)

PROCEDURES

Before beginning the test, DEMONSTRATE the MVV maneuver:

1. INSERT new mouthpiece and filter into the flow sensor.
2. SELECT from the test choice menu by pressing NUMBER 2
3. INSTRUCT patient in the maneuver with the following suggestions:
    - Put mouthpiece in your mouth, past your teeth, and form a tight seal with your lips. Make sure your tongue is not blocking the mouthpiece.
    - Breathe through mouthpiece as rapidly and deeply as possible. This should simulate breathing during hard exercise.
4. Press ENTER when patient's breathing is deep and regular for at least 12 seconds.

The FLOWMATE V PLUS will display a graphic rendering of the patient's breathing pattern.



5. Encourage patient to make the graph move up and down as rapidly as possible.
6. After 12 seconds have elapsed, have the patient remove the mouthpiece and relax. The unit will beep at the completion of a full exhalation after 12 seconds

7.When flow has stopped screen prompts: “Was the Patient Effort Acceptable? (press YES or NO)”

8. Press YES or NO.

- If YES the unit computes, displays and stores the test results. If AUTOPRINT option has been activated, the report is printed out.

NOTE: If the MVV graph is not printed at the time the numeric values are displayed on the screen, the graph will not be available later, but the MVV numeric values for up to two tests may be recalled later.

- If NO, the unit abandons the test and the patient can try again until clinician is satisfied with effort.

NOTE: Patient effort is acceptable if the patient:

- Made a maximum effort.
- Lasted a full 12 seconds.
- Did not cough.

FLOWMATE V PLUS displays results when patient test is accepted.

MVV TEST RESULTS SUMMARY

Index	Units	Meas.	Pred	%Pred	Var.
MVV	L	185	177	104	n/a
Rate	Breaths/M	55	n/a	n/a	n/a

Press DISPLAY to show graph

NOTE: The MVV test can be exhausting to some patients, especially the elderly or ill. Therefore, it should not be repeated without a rest period.

Press TEST to return to the TEST MENU.

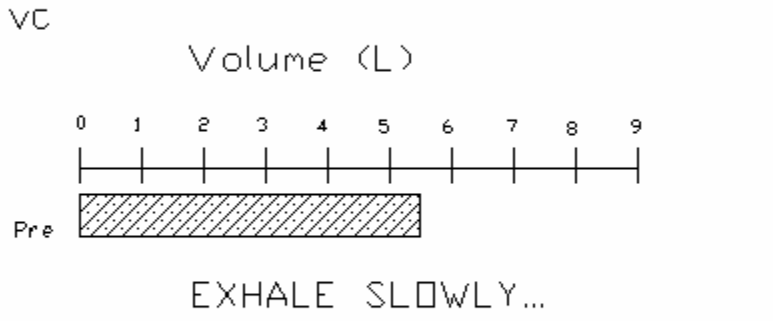
VITAL CAPACITY (VC) TEST PROCEDURES

Before beginning the test, DEMONSTRATE the VC maneuver so the patient has a clear idea of what is expected of him/her.

1. INSERT new mouthpiece and filter into the flow sensor.
2. SELECT from the test choice menu by pressing NUMBER 3.
3. INSTRUCT patient in the maneuver with the following suggestions
    - Take as deep a breath as possible and hold it.
    - Put mouthpiece in your mouth, past your teeth, and form a tight seal with your lips. Make sure your tongue is not blocking the mouthpiece.
    - Exhale slowly, push every bit of air out of your lungs.
    - Remove mouthpiece.

4. While exhaling, patient should look at the incentive display and try to move the bar as far to the right as possible.

ILLUSTRATION



5. When flow has stopped screen prompts: ***"Was the Patient Effort Acceptable? (press YES or NO)"***

6. Press YES or NO.

- If YES the unit computes, displays and stores the test results. If AUTOPRINT option has been activated, the report is printed out.
- If NO, the unit abandons the test and the patient can try again until clinician is satisfied with effort.

NOTE: Patient effort is acceptable if the patient:

- Made a maximum effort.
- Exhaled completely.
- Exhaled smoothly, without coughing.

FLOWMATE V PLUS displays results when patient test is accepted.

VC TEST RESULTS SUMMARY

Index	Units	Meas	Pred	%Pred	Var
VC	L	5.50	5.67	97	0.2

Press DISPLAY to show graph

METHACHOLINE CHALLENGE

OVERVIEW

The methacholine challenge test determines airways reactivity. It is useful for diagnosing "variant asthma" and to identify predictive factors in asthma patients.

- Variant asthma: An intermittent asthma which may occur during exercise, exposure to cold air, due to infections, or at night. The patient's baseline spirometry might appear normal, and there isn't a significant response to a bronchodilator, hence they appear to be non-asthmatic. A methacholine challenge test will demonstrate an abnormally high airways reactivity in patients with variant asthma.

- Predictive Factors: The degree of airways reactivity may be correlated with the severity of asthma symptoms and the duration or frequency of asthma attacks.

The methacholine challenge test is performed by inhaling successively increasing doses of methacholine, and measuring the change in FEV1 between each dosage level. The FEV1 is an important indice in this test.

PROCEDURES

1. From the MAIN MENU press NUMBER 1 (PATIENT)
2. Enter the Patient ID number and other information as previously described.
3. At the TEST MENU Press NUMBER 4 (CHAL)
4. Administer 5 breaths of diluent, press ENTER when ready for FVC test.

NOTE: Diluent is a saline solution with no methacholine in it. It is a placebo which will give a baseline spirometry reading. Once the diluent has been administered, and the ENTER key is pressed, the normal FVC routine is entered. The FVC test is administered as usual and all FVC and FEV_1 indices are the same as the normal FVC testing except for the test header.

1. INSTRUCT THE PATIENT:
    - Place noseclip on nose.
    - Take as deep a breath as you can and hold it
    - Put mouthpiece in your mouth, past your teeth, and form a tight seal with your lips. Make sure your tongue is not blocking the mouthpiece.
    - Now blast the air out as hard and fast as possible.
    - Inhale as deeply and quickly as possible through the mouthpiece.
    - Remove the mouthpiece.
2. Press TEST
    - The FLOWMATE V PLUS will prompt: ***"Do you want to increase the challenge dose? (YES, NO, or exhale for another FVC)"***

NOTE: Several baseline FVC tests should be performed until the %VAR is less than 5% or 0.2L, whichever variability method you have selected. Clinician/physician must determine whether to repeat another baseline test or continue with the challenge. They must also determine whether to continue another FVC for that dose, or whether to increase the dosage.

3. Press ENTER

The FLOWMATE V PLUS selects the best test according to the normal best test criteria, then checks to see if the FEV_1 %Pred is less than 70%. If results show that the FEV_1 is less than 70%, the FLOWMATE V PLUS displays a warning:

LOW FEV1: CHALLENGE NOT RECOMMENDED!! Press CLEAR to stop; ENTER for challenge test.

4. Press CLEAR to stop. The FLOWMATE V PLUS will revert back to the test selection prompt, but the baseline test is saved.

5. Press ENTER to continue the methacholine test.

Once ENTER is pressed, the normal FVC test routine remains the same, but the display and report for the challenge test are different. The index of primary interest is the FEV1. The display also has columns with BASE and %CHNG (for baseline readings)

Index	Unit	Meas.	Base	%Chng	%Var
FEV1	L	x.xx	x.xx	x.xx	xxx

NOTE: The FVC tests should be continued for this dosage until the %VAR is less than 5% or 0.2L, whichever variability method you have selected. Both indices are displayed.

6. Press TEST to continue testing after test results are displayed. You will see the following display:

Administer 5 breaths of xx.xx #x Press ENTER when ready for FVC test

Perform the following procedures:

1. Administer five (5) breaths There are up to five sequences of methacholine, labeled #2-6, and then one sequence (#7) of bronchodilator to open the airway back to normal.
2. Perform the FVC maneuver with a new dosage, and continue with that dosage until the VAR is within acceptable limits.
3. Administer Bronchodilator after a sequence of six tests have been performed or the patient's FEV_1 has dropped 20%. Press ENTER and perform another FVC test.
4. If the FEV_1 has dropped 20% from baseline the FLOWMATE V PLUS will display: ***"FEV_1 has dropped xx%, challenge complete. Press ENTER to continue."*** Press ENTER.
5. Screen will prompt***: "Do you want to end challenge? (YES, NO, or exhale for another)"***
6. Press YES to end methacholine challenge test.
7. Administer the Bronchodilator.

POST -BRONCHODILATOR TESTING

After giving the patient a series of baseline tests, you may want to administer a bronchodilator and then retest the patient to measure the effects of it. The FLOWMATE V PLUS calculates the differences in various Pre-BD and Post-BD indices. (BD= BronchoDilator) Any test on the TEST MENU can be performed both pre and post-BD by simply pressing PATIENT and following the postbronchodilator prompts.

1. From the MAIN MENU press NUMBER 1 -- PATIENT.
2. After re-entering the patient's ID number, press ENTER.
3. Display will prompt: ***"Is this Post BD?"***
4. Press YES for Post-BD testing.
5. Press NO if you want to continue Pre-BD testing

NOTE: Once you have flagged a patient as Post-BD, you can't remove the category unless you re-enter all the patient ID information, including a different ID number.

6. Press ENTER repeatedly to scroll through patient data until reaching the TEST options, or press CLEAR from the top of the information screen if you do not want to make changes in the current data.
7. Continue testing as usual. Post and Pre-BD testing procedures are similar. The only difference is that the test results will be labeled Pre or Post-BD on the Best Test Summary Report.

NOTE: In order to compare Post-BD with Pre-BD testing, the FLOWMATE V PLUS must have the patient's Pre-BD tests stored in memory. Therefore, take care not to erase patient's Pre-BD data.

RETRIEVING TEST RESULTS

After each test is completed and accepted, the FLOWMATE V PLUS automatically stores it in its memory. If you chose the Automatic Printout option during customization, the results of each test will automatically be printed. You can recall test data for displaying, printing, or erasing by following these steps:

1. From the MAIN MENU press 1 -- PATIENT
2. Enter patient ID number, then press ENTER

NOTE: If you are unable to remember the patient ID number, you may return to MAIN MENU by pressing the PATIENT key, then press SUMMARY to see a listing of the patient directory.

3. Press ENTER repeatedly to scroll through patient data until reaching the TEST options, or press CLEAR from the top of information screen if you do not want to make changes to the current data.
4. From the TEST MENU, press DISPLAY, then enter the test number of the test you are seeking data on.

NOTE: Each test for a given patient is given a test number of two digits (01,02,03, etc.) The number increased by one for each consecutive test on the patient, regardless of the type of test or whether it is pre or post-bronchodilator. This is the number you enter.

5. Use the DISPLAY key to scroll through the various test indices. The indices appear in the same order they are printed on the test report.
6. Use the PRINT key from the MAIN MENU to print tests of all or some of the patients. From the TEST MENU press PRINT to print out the current test results.

ERASING A TEST

Press ERASE

- From MAIN MENU to erase the tests of all or some of the patients
- From TEST MENU to erase the test data from a single patient.

NOTE: The FLOWMATE V PLUS will always confirm that you want to erase this data.

ERASE TEST PROCEDURE

1. From the TEST MENU, press ERASE.
2. Display will prompt: ***"Erase which test?"***
3. Enter the number of the test you want to erase
4. FLOWMATE V PLUS will confirm. Press YES to erase, NO to cancel.
5. From within the test results display, pressing the ERASE key will erase that particular test. Before erasing, the FLOWMATE V PLUS will ask for confirmation. Press YES to erase, NO to cancel.

NOTE: Once you press the YES key and the test record is erased, there is no recovery possible.

ERASE PATIENT FROM MEMORY

1. From the MAIN MENU, press ERASE.
2. Display will prompt:
   1. All records in memory
   2. Some records in memory
   0. Nothing
3. Selecting one (1) will delete all the patient records in memory. Selecting two (2) will allow the user to select specific patients to delete from the base memory. Selecting zero (0) or pressing the CLEAR key makes no changes to the base memory.
4. If one (1) or two (2) are selected, the FLOWMATE V PLUS will confirm. Press YES to erase, NO to cancel.

SAVING PATIENTS TO DISKETTE

1. From the MAIN MENU, press SEND. The diskette must be in the disk drive before pressing the SEND key.
2. Display will indicate records are being saved by the displaying message **"Sending unsaved records to diskette"**.

Pressing the send key while viewing a patient record, will send updated and previously unsaved test information about that patient to the diskette.

SUMMARY REPORTS

From TEST MENU, pressing the SUMMARY key prints out a Best Test Summary Report. Each report contains the following:

Report Header:	Indicates the type of test, number of test (to recall from memory), and date and time of test.
Index:	Indicates the names of the various test indices.
Unit:	Indicates that L=liters, L/M=liters per minute; and L/S= liters per second.
Meas:	Indicates the actual measured value for that index, in the units indicated in the "UNIT" column.
Pred:	Indicates the predicted value for the index, based on the patient data. If you skipped the patient data to go directly to testing, the FLOWMATE V PLUS prints "N/A" for "not applicable." It will also print "N/A" for indices not covered by a respective set of normals.
%Pred:	Compares the patient's measured result to the predicted normal result for that index, expressed as a percentage.
%Var or Var:	Indicates the variability or reproducibility of the test index, as compared to the best previous measured value for that

	index.This is reportable as a percentage or as absolute variant. For the FVC and FEV1 test, this value must be less than 5% or 0.20L for the test to be regarded as reproducible. Continue testing until the %Var or Var is less than 5% or 0.20L respectively.
Diff:	Indicates the variability of test indices, expressed as comparison in indices units, between Best Test Post-BD effort to Best Test Pre-BD effort.
%Diff:	Indicates the variability of test indices, expressed in percentage difference, between Best Test Post-BD effort and Best Test Pre-BD effort.

NOTE: The variability (%Var) does not appear on the first test taken since there are no indices in memory to compare it to.

CHAPTER 6
MAINTENANCE AND TROUBLESHOOTING

MAINTENANCE

The FLOWMATE V PLUS is designed to require a minimum of maintenance. The most important regular maintenance routine is the cleaning of the flow sensor. To clean the EASY CLEAN Cartridge, it must be unscrewed. Before beginning disassembling procedures, please note the following points:

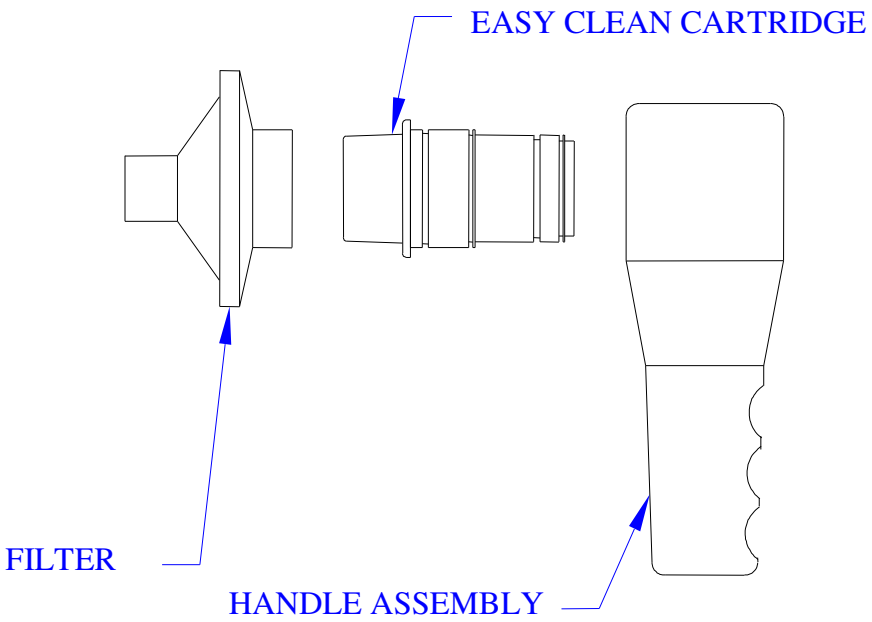
- Do not use alcohol on Flow Sensor or any other parts.
- To reduce the risk of cross contamination Spirometrics states that you replace the Filter Mouthpiece Housing between patients. The EASY CLEAN Cartridge's recommended cleaning schedule when the 2195 Filter Mouthpiece Housing is used, is monthly or every 60 patients, whichever comes first.
- When testing a patient with an active communicable disease, the EASY CLEAN Cartridge should be cleaned before reuse even when the 2195 Filter Mouthpiece Housing is used. This is especially important after you test any patient with an active communicable disease.
- ALWAYS UNPLUG THE FLOWMATE V PLUS BEFORE CLEANING TO AVOID ELECTRICAL SHOCK.

To disassemble the Flow Sensor, proceed with the following steps:

1. Remove filter system (disposable filter).
2. Hold Flow Sensor towards you as if about to test yourself, and grasp the sensor core with your hand.
3. Turn counter clockwise to unscrew EASY CLEAN Cartridge from Flow Sensor.
4. Pull out the EASY CLEAN Cartridge section from Flow Sensor when the threads disengage.

To clean the Flow Sensor, proceed with the following steps:

1. Clean the EASY CLEAN Cartridge element in cold sterilization fluid, preferably a protein-dissolving solution. Follow the manufacturer's instructions, thoroughly rinse in water and allow to dry completely.
2. Once the core element is **completely** dry insert back into Flow Sensor.
3. Align threads of EASY CLEAN Cartridge to threads of Sensor handle and screw clockwise.
4. Tighten until snug. DO NOT exert high torque in screwing together, or internal alignment pins may be broken holding the sensor core in position. A snug fit is all that is required.
5. Replace filter.



To disassemble the Flow sensor unscrew the core assembly counterclockwise
To assemble the Flow Sensor screw in the Core Element clockwise

CLEANING AND SANITIZING

In addition to regular cleaning of the flow sensor as described above, the remaining parts of the FLOWMATE V PLUS may become soiled and require occasional cleaning or sanitizing.

1. ALWAYS UNPLUG THE FLOWMATE V PLUS BEFORE CLEANING TO AVOID ELECTRICAL SHOCK.
2. The base unit and the handle assembly may be cleaned with a soft cloth dampened with water or a mild disinfectant soap. Squeeze all excess water from the cloth before wiping the unit. DO NOT allow any water to enter the printer slot or any other opening on the unit.
3. External surfaces of the unit may be sanitized by gently wiping with a disposable germicidal cloth such as a Sani-Cloth®.
4. DO NOT use abrasives or harsh chemical solutions to clean the unit.
5. The FLOWMATE V PLUS is not waterproof or autoclavable.

Spirometrics Medical Equipment Co. will make available on request circuit diagrams, component part lists, and descriptions which will assist the USER's appropriately qualified technical personnel to repair those parts which are designated by the manufacturer as repairable.

TROUBLESHOOTING

If your FLOWMATE V PLUS is not operating properly, try the procedures outlined in this section. If any problems persist, or seem too complex to solve immediately, technical questions may be addressed by calling 207-657-6700, or by e-mail at spiro@spirometrics.com or 800-767-0004.

IF PROBLEM IS THIS....	**ASK THESE QUESTIONS...**	**IF ANSWER IS YES....**	**IF ANSWER IS NO...**
No message on display	Is FLOWMATE V PLUS plugged into power supply?	Continue	Plug unit into power supply
	Is power supply plugged in?	Continue	Plug power supply into outlet.
	Is there power to the outlet?	Contact service department	Check circuit breaker or power source.
Printer Not Responding message on display	Is there sufficient paper in unit?	Continue	Insert roll of #2128 thermal paper into unit.
	Is the paper release lever in the up position?	Contact Service Dept.	Push paper release lever into the up position.
(External Printer)	Is the external printer selected?	Continue	Select the external printer from Customization Menu.
	Is the external printer ON and ON LINE?	Continue	Select ON LINE on the printer controls.
	Is the appropriate printer cable (#3355) being used?	Continue	Attach cable #3355 to FLOWMATE V PLUS and printer.
	Is printer still not operating correctly?	Contact Service Department	

IF PROBLEM IS THIS....	ASK THESE QUESTIONS...	IF ANSWER IS YES....	IF ANSWER IS NO...
Paper advances, but no print shown	Are you using #2128 thermal paper?	Continue	Insert roll of #2128 thermal paper into unit.
	Is paper release lever in UP position?	Continue	Push paper release lever into the UP position.
	Is printer operating correctly?		Check paper position and if necessary reinstall roll with paper feeding from back of roll.
FLOWMATE V PLUS does not respond to testing	Is the tubing connected to FLOWMATE V PLUS?	Continue	Connect tubing to fittings on back of unit.
	Is the tubing kinked between base and Flowsensor?	Continue	Un-kink tubing.
VOLUME reported larger or smaller than expected	Does the unit show acceptable results when performing calibration linearity check?		Failure to obtain acceptable results from the linearity check, see section on calibration.
FLOWMATE V PLUS does not maintain accurate Date and or Time	How long is the unit turned on for during the course of a week?		The unit only charges when the unit is turned on, and to maintain the internal battery's charge it must be run 20 – 24 hours a month. That can be broken up into as little as 6 – 8 hours each week.

Calibration:

This section contains possible solutions for calibration problems.

Problem	Solution
Can not keep the calibration puck within the tolerance window in the calibration routine.	Calibration of the Flow Sensor requires a steady even injection from the calibration syringes. Check the Following... • The proper reference value of the calibration syringe is entered. ie., 3Liter value for a 3Liter Calibration Syringe. • The calibration syringe does not leak air. • The adapter seal for air leakage-make sure it provides a tight seal around the syringe nozzle and the filter system. • The filter system is snugly connected to Flow Sensor. • The Easy Clean Cartridge snuggly screwed into the outer core housing. • Is Core free from moisture buildup?
When performing linearity check at different flow rates, the reported values exceed the +/- tolerances.	Check the Following... • The proper reference value of the calibration syringe is entered. ie., 3Liter value for a 3Liter Calibration Syringe. • The calibration syringe does not leak air. • The adapter seal for air leakage-make sure it provides a tight seal around the syringe nozzle and the filter system. • The filter system is snugly connected to Flow Sensor. • The Easy Clean Cartridge snuggly screwed into the outer core housing. • Is Core free from moisture buildup? Perform calibration linearity check to verify that any changes have corrected the earlier problem.
The calibration graph will not move within the tolerance window of the calibration routine and the sensor will not detect flow.	Check that the core element is properly installed. This requires complete insertion of the core element into the handle assembly. Refer to the maintenance section for assembly instruction.

Patient Storage:

This section contains possible solutions to patient storage problems.

Problem	Solution
FLOWMATE V PLUS will not store more than 7 patients in the base memory.	The FLOWMATE V PLUS will store 7 patients in its base memory. If you need more storage you can save to a diskette, by pressing the SEND key. See Chapter 4
When saving to diskette and "Disk Error" message appears	Diskette may not be formatted correctly. The FLOWMATE V PLUS requires that any diskette used be formatted before using. Diskette must be a 1.44 MB, not a 720 k. IBM-PC format. Is diskette write protected?

Problem	Solution
Can not recall a stored patient.	Storage of patient data is automatic in the base memory. Patients are stored by patient ID, when patient data is first entered. To determine what is stored in the FLOWMATE V PLUS's memory: • Press the SUMMARY key at the Main MENU. Make sure the spirometer is customized to the type of printer being used. A list of patients stored by ID number and age will be displayed. To print a list, press the PRINT key. • To search for patients on a disk, insert disk into drive and select YES to the "List patients on a diskette?" prompt.

NOTE: The patient storage memory will always discard the earliest patient once the FLOWMATE V PLUS reaches the maximum patient storage. Always print or erase patients in storage or send the patient information to a floppy disk for additional storage.

CHAPTER 7

FLOWMATE V PLUS SPECIFICATIONS

PHYSICAL

Height	5.5”	(14.0 cm)
Depth	9.0”	(22.9 cm)
Width	11.375”	(28.9 cm)
Weight	10.5 lbs.	(4.8 kg)

POWER REQUIREMENTS

Voltage	100-240 VAC, 50-60Hz
Amperage	1.0A to 500 Milliamps (As supplied to the external power supply)
Wattage	45 Watts maximum

POWER CONNECTION

IEC standard three prong connector with ground. Permits wide variety of international primary power connector cord sets. Supplied with hospital grade plug USA and Canada.

The power supply cord serves as the MAINS (power) disconnect for the power supply.

ENVIRONMENTAL

Temperature Operating Range	50°F to 104°F	(10°C to 40°C)
Maximum storage temperature	158°F	(70°C)

USER INTERFACE

Display	256 by 128 graphic LCD display
Keypad	26 key membrane switch keypad with tactile feedback.

PATIENT DATA

ID number	Up to 16 digits including, periods (.), and slashes (/). Do not start with either a period (.) or a slash (/) however.
Age	1 to 99
Sex	Male, Female
Race	Caucasian, Black, Non-Caucasian, Hispanic, Asian
Height	Up to three digits, in inches or centimeters.
Weight	Up to three digits (optional entry) Customizable as lbs. or kgs.
Smoke	0-60 cigarettes per day.

TEST MANEUVERS

FVC	Forced Vital Capacity
MVV	Maximum Voluntary Ventilation
VC	Vital Capacity (Otherwise known as Slow VC)
Challenge	Methacholine Challenge

INDICES CALCULATED

FVC maneuver

FVC	Forced Vital Capacity
FEV1	1 second Forced Vital Capacity
FEV 3	*3 second Forced Vital Capacity
FEV1/FVC%	% FEV1 Ratio
FEF25-75	Mid Expiratory Flow Rate
FEF75-85	*Late Expiratory Flow Rate
FEF200-1200	*Forced Expiratory Flow Rate between 200ml and 1200 ml
FEF50	*Forced Expiratory Flow Rate at 50% of FVC
PEF	Peak Expiratory Flow
FIVC	*Forced Inspiratory Vital Capacity
FIF50	*Forced Inspiratory Flow at 50% of FVC
FEF50/FIF50	*Ratio of FEF50 to FIF50
PIF	*Peak Inspiratory Flow
COPD	**Risk Assessment [1]
Lung Age	**Lung Age Assessment based on FEV1 [2]

NOTE: FEV timing is based on back extrapolation
* - these indices appear on the expanded reports
** - these indices appear on the summary report

MVV maneuver

MVV volume	Volume Expired per minute
MVV rate	Breaths per minute

VC maneuver

VC	Vital Capacity
ATI	Air Trapping Index

Challenge

FVC	Forced Vital Capacity
FEV1	1 Second Forced Vital Capacity
PD20	Provocative Dose

---

[1] Higgins, Millicent W., M.D. and Keller, Jacob B., M.P.H., Estimating your patient's risk COPD, J Respir Dis 4(1):97-108, 1983.

[2] Morris, James F., M.D. and Temple, William, Spirometric "Lung Age" Estimation for Motivating Smoking Cessation, Preventive Medicine 14, 655-662, 1985.

FLOW SENSOR

Maximum Flow Rate	+/- 16 liters/second
Accuracy	+/- 3%
Resolution	12 bit signed A/D
Sampling Rate	150Hz
Back Pressure	1.1 cmH20/L/s@14L/S
BTPS	Calculated automatically based on user input for environmental conditions.
Temperature	40° to 104°F 10° to 40°C
Barometric Pressure	20 to 35 inches of mercury 500 to 900 millimeters of mercury Input values determines units automatically

BEST TEST DETERMINATIONS (pertains to FVC trials only)

FVC	Largest regardless of test
FEV1	Largest regardless of test
Ratio	Combination of Best FEV1/Best FVC
Flow Rates	Taken from the trace with the greatest sum of FVC and FEV1
Patient Effort	Requires clinician to evaluate acceptable or unacceptable patient effort. Discards tests the clinician deems as unacceptable.
Variability	Compares indices of current test with best test in memory. Displays and prints variability as % or as absolute difference (user selectable in customization). Variability greater than 5% or 0.2L (depending on user selection) for the FVC and/or the FEV1 is regarded as poor reproducibility.
Expiratory Time	If forced expiratory time is less than 6 seconds, a “TEST TOO SHORT” message will be displayed.
Extrapolated Volume	If extrapolated volume is greater than 5% of the FVC, and or $\geq$ 0.20 L a “SLOW START” message will be displayed.
Interpretations	Obstruction, Restriction, or Ventilatory disorder.

INPUT/OUTPUT COMMUNICATION PORTS

Graphic Output	Printouts according to ATS scale specifications when user selects option within customization (Scale Factors: Volume is 10 mm/L, Flow is 5 mm/L/s, and Time is 20 mm/s).
Printer Options	Internal thermal printer using 112mm wide thermal paper. External printer with selectable print drivers within customization. Standard DB-25 Female IBM PC pin out to standard centronic connection.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1-1 harmonized standard.

Serial Port	Currently no user defined function for the serial connection.
Patient Storage	Internal minimum of 7 patients (variable depending on number of FVC tests performed and saved) External storage on 1.44 Mb formatted disk minimum 45 patients (variable depending on number of FVC tests performed and saved) FVC - 6 trials each patient MVV - 6 trials each patient VC - 6 trials each patient
Test Numbering	Numbers each patient trial that is accepted consecutively regardless of the type of test for recall later.

INSTRUMENT CALIBRATION

Syringe	Selectable from 1 to 9 liters at ATPS. Daily calibration is recommended on days testing is to be performed. Calibration reports print out automatically if printer is connected and is on-line.

EQUIPMENT CLASSIFICATION

Class 1 Equipment
Class BF Applied Part
Ordinary Equipment – (enclosed equipment without protection against ingres of water. Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC mixture with air or with OXYGEN or NITROUS OXIDE.)

SAFETY COMPLIANCE

The FLOWMATE V PLUS has been evaluated and found to comply with the applicable requirements of the Standard UL2601-1 'Medical Electrical Equipment, Part 1: General Requirements for Safety' 2nd Edition including Amendments 1 and 2, CAN/CSA C22.2 No. 601.1-M90, 'Medical Electrical Equipment-Part 1: General Requirements for Safety', including C22.2 No. 601.1 S1-94 (IEC601-1, Amendment 1:1991) Supplement No. 1-94 to CAN/CSA 22.2 No. 601.1-M90.

EMI COMPLIANCE STATEMENT

The FLOWMATE V PLUS has been tested to IEC 601-1-2 : 1993 and EN55011 : 1991 and found to comply with the criteria for laboratory equipment.

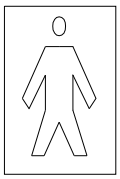
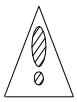
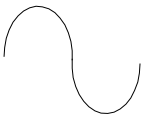
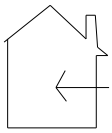
TRANSPORT AND TEMPORARY STORAGE

The FLOWMATE V PLUS has been packaged for transport and shipping for an ambient temperature between -40ºC to 70ºC and a relative humidity range of less than 100% non-condensing. The shipping package should not get wet, as possible damage to the device can occur.

EMBEDDED MICROPROCESSOR

The FLOWMATE V PLUS utilizes an Intel embedded microprocessor for control and calculations.

Markings used on Device and / or Power Supply:

Symbol	Description
⎓	Direct Current
	Type BF Equipment
	Attention, consult ACCOMPANYING DOCUMENTS
	Alternating Current
	Indoor Use
	Off (power: disconnection from the Mains)
	On (power: connection to the Mains)
	Protective earth ground
	Safety Mark of Intertek Testing Services NA Inc. to applicable standards

CHAPTER 8

NORMALS TABLES

One of the principal functions of a spirometer is to determine whether a patient's pulmonary function is normal or abnormal. A "predicted normal" value for a spirometric test index is a "prediction" of the value a patient SHOULD attain if he/she were "normal". The predictions are based on extensive studies of a population done by leading pulmonologists. To obtain predicted values the technician must enter the height, age, sex and race. The spirometric test indices from thousands of people of different height, age, sex and race were analyzed and compiled into an equation. Each normals table is named by the pulmonologist who led the study.

NORMALS TABLES

The FLOWMATE V PLUS has normals tables from the following five studies stored in memory. Select the table you want to use in Customizing the FLOWMATE V PLUS on pg. 8. Note the applicable indices and ranges for each study.

Knudson 1983

INDICES	SEX	AGE Yrs -Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FVC				
FEV1	FEMALE:	6 - 10	106.7 - 147.3	42 - 58
FEV1/FVC		11 - 19	132.1 - 182.9	52 - 72
FEF 25-75		20 - 69	147.3 - 180.3	58 - 71
FEF 50		70 - 87	147.3 - 167.6	58 - 66
	MALE:	6 - 11	111.8 - 154.9	44 - 61
		12 - 24	139.7 - 193.0	55 - 76
		25 - 84	157.5 - 195.6	62 - 77

Crapo

INDICES:	SEX	AGE Yrs - Min-max	HEIGHT cm. Min-max	HEIGHT in. Min-max
FVC	FEMALE	17-84	146-178	57-71
FEV1	MALE	15-91	157-194	61-77
FEV3				
FEV1/FVC%				
FEF 25-75%				
MVV vol				

ECCS with Knudson 1983 Children (ages 18 - 24 are evaluated as age 25)

INDICES	SEX	AGE Yrs, Min - max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FVC	FEMALE:	25 - 90	145.0 - 180.0	56 - 72
FEV1	CHILDREN: (female)	6 - 10	106.7 - 147.3	42 - 58
FEV1/FVC		11 - 17	132.1 - 182.9	52 - 72
FEF 25-75	MALE:	25 - 90	155.0 - 195.0	58 - 80
PEF	CHILDREN: (male)	6 - 11	111.8 - 154.9	44 - 61
FEF 50		12 - 17	139.7 - 193.0	55 - 76
FIVC				
MVV vol				
VC				

Morris

INDICES	SEX	AGE yrs - Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FVC	FEMALE:	20 - 84	145.0-180.0	56 - 72
FEV1				
FEV1/FVC	MALE:	20 - 84	155.0-195.0	58 - 80
FEF .1 - 1.2				
FEF 25-75				
FEF 75-85				

HSU 1979 (Using Journal of Pediatrics 1979)

INDICES	SEX	AGE yrs- Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FVC	FEMALE:	7 - 20	111 - 180	43 - 71
FEV1	MALE:	7-20	111 - 190	43 - 75
FEF 25-75				
PEF				

LAM 1982

INDICES	SEX	AGE yrs- Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FVC	FEMALE:	5 - 74	Height range not specified in study.	Height range not specified in study.
FEV1	MALE:	5 - 74	Height range not specified in study.	Height range not specified in study.
PEF				

COMPOSITE

This is the Default normals selection. These normals provide predicted values for most indices.

INDICES	AUTHOR
FVC	Knudson 83
FEV1	Knudson 83
FEF 50	Knudson 83
FEV3	Crapo
FEF 25-75	Knudson 83
FEF 75-85	Morris
PEF	ECCS
FIVC	Knudson 83
FIF 50	No Predicted
PIF	No Predicted
FEV1/FVC	Knudson 83
FEF 2-1.2	Morris
MVV Vol	Crapo
VC	Knudson 83

ATPS and BTPS

BTPS: The air in the patient's lungs is said to be "BTPS conditions". BTPS is an abbreviation for Body Temperature, Standard Pressure, and Saturated with water vapor.

ATPS: The air measured by the Flow Sensor is said to be at "ATPS conditions". ATPS is an abbreviation for the Ambient Temperature, Standard Pressure, and Saturated with water vapor.

AUTOMATIC EXPIRATORY BTPS CALCULATION: The air inside the patient's lungs is at body temperature (98.6 degrees Fahrenheit or 37 degrees Centigrade). A patient exhales into the Flow Sensor, the air cools. As the air cools, it contracts and becomes a smaller volume than it was in the patient's lungs. The volume you want to measure is the larger volume in the patient's lungs, not the smaller volume measured by the Flow Sensor.

To calculate the volume of air in the patient's lungs, the FLOWMATE V PLUS automatically multiplies the volume measured by the Flow Sensor. The correction factor is based on temperature present in the testing room.

NOTE: Barometric pressure must be entered in Calibration Refer to Pg. 37

AUTOMATIC INSPIRATORY BTPS CALCULATIONS: The air that the patient inspires through the Flow Sensor is at ambient temperature (the temperature of the immediate surroundings). As the patient inhales through the Flow Sensor, the air heats up in the lungs. As the air heats up it expands and becomes a larger volume than it was before. The volume you want to measure is the larger volume in the patient's lungs, not the smaller volume measured by the Flow Sensor.

To calculate the volume of air in the patient's lungs, the FLOWMATE V PLUS automatically multiplies the volume measured by the Flow Sensor and the BTPS correction factor. The inspiratory BTPS correction factor for the FLOWMATE V PLUS is variable, based on the air temperature and average standard barometric pressure you entered in the Calibration Routine.

BTPS Correction Factors

The FLOWMATE V PLUS automatically corrects to give you BTPS readings. This chart is included for reference purposes only. You calculate the BTPS correction factor by determining the ambient temperature and locating the corresponding BTPS correction factor on this table at 760mmHg barometric pressure.

AMBIENT TEMPERATURE (degrees)		BTPS EXPIRATORY FACTOR
C°	F°	
10	50.0	1.125
11	51.8	1.120
12	53.6	1.115
13	55.4	1.110
14	57.2	1.105
15	59.0	1.100
16	60.8	1.095
17	62.6	1.090
18	64.4	1.085
19	66.2	1.079
20	68.0	1.074
21	69.8	1.069
22	71.6	1.064
23	73.4	1.058
24	75.2	1.053
25	77.0	1.047
26	78.8	1.042
27	80.6	1.036
28	82.4	1.030
29	84.2	1.025
30	86.0	1.019
31	87.8	1.013
32	89.6	1.007
33	91.4	1.001
34	93.2	1.000
35	95.0	1.000
36	96.8	1.000
37	98.6	1.000
38	100.4	0.993
39	102.2	0.986
40	104.0	0.979

Feet / Inches / Centimeters Conversion Chart

FEET	INCHES	CENTIMETERS	FEET	INCHES	CENTIMETERS
3'0"	36"	92	5'4"	64"	163
3'1"	37"	94	5'5"	65"	165
3'2"	38"	97	5'6"	66"	168
3'3"	39"	99	5'7"	67"	171
3'4"	40"	102	5'8"	68"	173
3'5"	41"	105	5'9"	69"	176
3'6"	42"	107	5'10"	70"	178
3'7"	43"	110	5'11"	71"	181
3'8"	44"	112	6'0"	72"	183
3'9"	45"	115	6'1"	73"	186
3'10"	46"	117	6'2"	74"	188
3'11"	47"	120	6'3"	75"	191
4'0"	48"	122	6'4"	76"	193
4'1"	49"	125	6'5"	77"	196
4'2"	50"	127	6'6"	78"	198
4'3"	51"	130	6'7"	79"	201
4'4"	52"	132	6'8"	80"	204
4'5"	53"	135	6'9"	81"	206
4'6"	54"	138	6'10"	82"	209
4'7"	55"	140	6'11"	83"	211
4'8"	56"	143	7'0"	84"	214
4'9"	57"	145	7'1"	85"	216
4'10"	58"	148	7'2"	86"	219
4'11"	59"	150	7'3"	87"	221
5'0"	60"	153	7'4"	88"	224
5'1"	61"	155	7'5"	89"	226
5'2"	62"	158	7'6"	90"	229
5'3"	63"	160	--	--	--

Pounds / Kilograms Conversion Chart

LBS	KGS	LBS	KGS	LBS	KGS	LBS	KGS
50	23	100	45	150	68	200	91
51	23	101	46	151	69	201	91
52	24	102	46	152	69	202	92
53	24	103	47	153	70	203	92
54	25	104	47	154	70	204	93
55	25	105	48	155	70	205	93
56	25	106	48	156	71	206	94
57	26	107	49	157	71	207	94
58	26	108	49	158	72	208	95
59	27	109	50	159	72	209	95
60	27	110	50	160	73	210	95
61	28	111	50	161	73	211	96
62	28	112	51	162	74	212	96
63	29	113	51	163	74	213	97
64	29	114	52	164	75	214	97
65	30	115	52	165	75	215	98
66	30	116	53	166	75	216	98
67	30	117	53	167	76	217	99
68	31	118	54	168	76	218	99
69	31	119	54	169	77	219	100
70	32	120	55	170	77	220	100
71	32	121	55	171	78	221	100
72	33	122	55	172	78	222	101
73	33	123	56	173	79	223	101
74	34	124	56	174	79	224	102
75	34	125	57	175	80	225	102
76	35	126	57	176	80	226	103
77	35	127	58	177	80	227	103
78	35	128	58	178	81	228	104
79	36	129	59	179	81	229	104
80	36	130	59	180	82	230	105
81	37	131	60	181	82	231	105
82	37	132	60	182	83	232	105
83	38	133	60	183	83	233	106
84	38	134	61	184	84	234	106
85	39	135	61	185	84	235	107
86	39	136	62	186	85	236	107
87	40	137	62	187	85	237	108
88	40	138	63	188	85	238	108
89	40	139	63	189	86	239	109
90	41	140	64	190	86	240	109
91	41	141	64	191	87	241	110
92	42	142	65	192	87	242	110
93	42	143	65	193	88	243	110
94	43	144	65	194	88	244	111
95	43	145	66	195	89	245	111
96	44	146	66	196	89	246	112
97	44	147	67	197	90	247	112
98	45	148	67	198	90	248	113
99	45	149	68	199	90	249	113

ACCESSORIES + REORDER INFORMATION

The following is a list of accessories and model numbers for the FLOWMATE V PLUS Spirometry System.

Description	Model #
FLOWMATE V PLUS Spirometer	4000
Nose Clips (Pkg. of 100)	2104
Filter, Disposable - Single Patient Use (Box of 100)	2195
3-Liter Calibration Syringe	2125
Adapter Seal, Calibration Syringe	30-0015
Spirometer, EASY CLEAN Cartridge (FLOWMATE V PLUS)	18225
Printer Cable	3355
Spirometer, AC Adapter (16 VDC, 2.8A) (Ault Inc. external power supply model SW154)	17002
FLOWMATE V PLUS Operator's Manual	4000M

Call your local distributor for more information on FLOWMATE V PLUS Accessories.

Printers available through Spirometrics
Please contact Inside Sales for complete computer / printer options.
207-657-6700
or
800-767-0004

Fax 207-657-4123

www.spirometrics.com

email spiro@spirometrics.com